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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,530	09/15/2003	Chi-Tang Ho	RU-0177-CON	3585
20583	7590	05/01/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			WARE, DEBORAH K	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/663,530

Applicant(s)

HO ET AL.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11, 12 and 15-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 12 and 15-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/16/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 11-12 and 15-36 are presented for reconsideration on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on February 10, 2006, was received. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

The amendment filed January 31, 2006, has been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 15 and 36 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 99/43314 (Shaikenov et al.) previously cited on a PTO-892 Form as set forth below.

Claims are drawn to methods for preventing or treating cancer in an animal comprising administering to an animal an effective amount of the composition of an extract of *Inula britannica*.

Shaikenov et al. teach a composition comprising an extract of *Inula Britannica* or compounds isolated therefrom comprising sesquiterpene lactone. Note 19, lines 15-21 and page 23, lines 12-25. Further, a method for treating cancer in an animal comprising administering to an animal an effective amount of the composition is also disclosed. See the abstract and page 23, lines 20-27. At page 60, line 23, human cancer is disclosed to be treated.

The claims are identical to the disclosure of Shaikenov et al. and are therefore, considered to be clearly anticipated by the teachings therein.

Response to Arguments

The argument filed January 31, 2006, is not persuasive because although the induction of phosphorylation of Bcl-2 is not specifically mentioned, such induction would be inherent to the administering of the disclosed extract of which is disclosed for treatment of cancer in humans.

The extract is disclosed to be obtained from the whole plant which includes the floral parts thereof. At page 19, lines 15-21 it is taught that such extracts are obtained from these plant parts. Therefore, the rejection is maintained over these claims 1, 15 and 36. Note that the courts have found that "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition" (i.e. extract of *Inula britannica*) "patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In *re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under

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37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 11-15 and 15-36 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO patent as cited above in view of Zhou et al for reasons of record.

These claims are discussed above and are further drawn to 1-O-acetylbritannilactone or 1,6-O,O-diacetylbritannilactone.

Shaikenov et al. teach a composition comprising an extract of *Inula Britannica* or compounds isolated therefrom comprising sesquiterpene lactone. Note 19, lines 15-21 and page 23, lines 12-25. Further, a method for preventing or treating cancer in an animal comprising administering to an animal an effective amount of the composition is also disclosed. See the abstract and page 23, lines 20-27.

Zhou et al. clearly teach 1-O-acetylbritannilactone or 1,6-O,O-diacetylbritannilactone which are isolated from *I. britannica*.

The claim differs from the teaching of the cited patent in that the specific compounds as noted above are not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was filed to provide for a methods as disclosed by the cited patent comprising 1-O-acetylbritannilactone or 1,6-O,O-diacetylbritannilactone as disclosed by Zhou et al. because these selected compounds are also disclosed to be isolatable from *I. Britannica* extracts, note page 249, col. 1, all lines. Clearly one of skill would have

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been motivated to select for these two lactones as well since sesquiterpene lactones from *I. Britannica* are clearly disclosed by the primary reference to be comprised in compositions formed from plant extracts of *I. Britannica*. To select for various concentrations and amounts thereof is well within the purview of an ordinary artisan. In the absence of persuasive evidence to the contrary the claim is deemed *prima facie* obvious over the cited prior art combination. The two selected lactones are well known and to select for one or the other of these two lactones is well within the purview of an ordinary artisan, especially since they are disclosed to possess cytotoxic activity.

Response to Arguments

The argument filed January 31, 2006, has been received and entered but not found persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The knowledge available at the time the claimed invention was filed is that extracts of *Inula britannica* can be administered to humans for treating cancer. These

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compounds include 1-O-acetylbritannilactone and 1,6-O,O-diacetylbritannilactone.

Therefore, one of skill would have expected successful results based upon these teachings of the cited prior art. Further, one of skill would have been motivated to administer these compounds to humans for treating cancer. The art teaches or suggests the claimed subject matter.

Therefore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The prior art combination clearly shows that administering the extract containing these ingredients for treating cancer is known or at least suggested to provide successful results. One of skill would have been motivated to optimize amounts for sufficient treatment of cancer as disclosed by the WO patent. The claims remain prima facie obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 11-12 and 15-36 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-6 of U.S. Patent No. 6,627,623. Although the conflicting claims are not identical, they are not patentably distinct from each other because the identical compounds are found in the Inula Britannica extract and used in a method of treating cancer.

The claims of the instant case would have been obvious over the patented claims based on the similar scope of the claimed subject matter. One of skill would have been motivated to administer the compound for a method of remedying cancer. Claims are therefore, obvious over the patented claims.

Response to Arguments

The argument filed January 31, 2006, has been received and entered. The upcoming consideration by Applicants upon notification of allowable subject matter is noted, however, since no claims are deemed allowable then the rejection is sustained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0927. The fax phone numbers for the organization is 571-273-8300.


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 128/1651


Deborah K. Ware
1651
April 10, 2006